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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,213	04/12/2001	Harukazu Fukami	001560-390	3646

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EXAMINER
HABTE, KAHSAY

ART UNIT	PAPER NUMBER
1624	7

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,213	FUKAMI ET AL.	
	Examiner	Art Unit	
	Kahsay Habte, Ph. D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 11-24* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-6 and 13-24, drawn to quinazolines.

Group II, claim(s) 11-12, drawn to sulfonylurea derivatives.

The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1, they lack the same or corresponding special technical feature for the following reasons: Groups I (quinazolines) and Group II (sulfonylurea derivatives) are directed to structurally dissimilar compounds and that the variable core structure do not belong to the same recognized class of chemical compounds in the art and have different special technical features, and references anticipating one invention, would not render obvious the others. For example the special technical feature of Group I are quinazoline ring attached to sulfonyl (i.e. hetero ring present) and is not present in Groups II. The special technical features of Group II are that it is an ester (non-hetero ring) and this special technical feature is not seen in Group I. In each case the special technical feature is essential to the utility of the compounds. Each group have a

special technical feature and are made and used independently of each other and could support separate patents. One skilled in the art would not consider such diverse special technical features equivalents of each other.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Donna Meuth on April 15, 2002 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-6 and 13-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-12 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Note

2. Page 45 (in the claims section) is missing. It is also noted that applicants use 43/1 and 46/1 instead of using consecutive numbering system.

Abstract

3. The abstract is defective, because there is no definition for **A** and $\mathbf{R^1}$ substituents. It is also recommended that applicants name the utility of the compounds. The compounds "useful as medicament" is very broad.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 5,814,631 (Fukami et al.). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8 of the said reference recites: "R^1 and R^2 as C_1 to C_4 lower alkyl which may be substituted by a carboxyl group" that is the same as the instant application. Since the cited reference recite the following substituents: R1 = C_1 to C_4 lower alkyl that can be substituted by a carboxyl group, R2 = hydrogen that are the same as applicants, a double-patenting rejection is proper.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fukami et al. (US Pat. No. 5,814,631). The cited reference on column 52 (example 148) teaches the synthesis of 3-(4-aminobenzenesulfonyl)-7-chloro-2,4(1H,3H)-quinazolinedione. The said compound is exactly the same as applicants except that it is excluded by the proviso. Applicants claim 2-aminobenzenesulfonyl and 3-aminobenzenesulfonyl, but excluded the 4-aminobenzenesulfonyl. First of all it is a

position isomer (see below for further discussion). Secondly, in the reference the substituents on the A ring are floating (see formula I). Thirdly, the cited reference also teaches substituents on the 2 or 3 positions (see example 127 on column 48).

It is well established that position isomers are prima facie structurally obvious even in the absence of a teaching to modify. The isomer is expected to be reparable by the same method and to have generally the same properties. This expectation is then deemed the motivation for preparing the position isomers. This circumstance has arisen many times. See: *Ex parte Englehardt,* 208 USPQ 343, 349; *In re Mehta,* 146 USPQ 284, 287; *In re Surrey,* 138 USPQ 67; *Ex Parte Ullyot,* 103 USPQ 185; *In re Norris,* 84 USPQ 459; *Ex Parte Naito,* 168 USPQ 437, 439; *Ex parte Allais,* 152 USPQ 66; *In re Wilder,* 166 USPQ 545, 548; *Ex parte Henkel,* 130 USPQ 474; *Ex parte Biel,* 124 USPQ 109; *In re Petrzilka,* 165 USPQ 327; *In re Crownse,* 150 USPQ 554; *In re Fouche,* 169 USPQ 431; *Ex parte Ruddy,* 121 USPQ 427; *In re Wiechert,* 152 USPQ 249, *In re Shetty*, 195 USPQ 753.

For example, "Position isomerism has been used as a tool to obtain new and useful drugs" (Englehardt) and "Position isomerism is a fact of close structural similarity" (Mehta, emphasis in the original). See also MPEP 2144.09, second paragraph.

Since the only difference between the compound of the cited reference and applicants is a position isomer, it would have been obvious to a person of ordinary skill in the art at the time of the invention was made to change the positions of the substituents on the phenyl to avoid prior art.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 13-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been added a proviso in claim 1, but there is no descriptive support in the specification for the said proviso. The proviso lacks description. Even a negative limitation requires description, *Ex Parte Grasselli,* 231 USPQ 393.

8. Claims 14-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 14-17, there has been recited a method of prevention of cardiac insufficiency, hypercardia, etc. The specification does not teach how to prevent the said diseases. The skill level in the art is so low, that the only way available is to treat the said diseases but not preventing someone from having the said diseases at first place.

9. Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for most of the diseases, does not reasonably provide enablement for non-diabetic renal disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to understand the invention commensurate in scope with these claims. There has been recited the treatment of non-diabetic renal disorders, but the specification does not teach the treatment of non-diabetic renal disorders. "Non-diabetic renal disorder" is any renal disorder that is not caused by diabetes. The said phrase is extremely broad and it includes every renal disorder that is out there except those from diabetes.

There has been recited the treatment of renal system in general, but renal system disorders vary in nature one from the other. As known the kidney has several essential roles:

1. Filter waste out of the blood; 2. Retaining protein, glucose, minerals, and water; 3. Maintain balance of electrolytes, sodium, potassium and phosphorus; 4. Calcium absorption; 5. Make hormones that produce red blood cells; 6. Produce renin, which regulates water retention and influences blood pressure. The disorders vary one from the other. For example, Kidney Stones that are defined as a hard mass of calcium and oxalate or phosphates that separate from the urine and build up on the inner surfaces of the kidney. There are also struvite stones caused be infection in the urinary tract. Much less common are the uric acid stone and the rare cystine stone. Renal tubular acidosis,

Cystic kidney diseases, and metabolic disorders (i.e. hyperparathyroidism) are also suspected of causing stones. Kidney infection is another renal disorder. Infection in kidney that is also called Pyelonephritis, it usually is from bacteria that spread from the bladder Causes can include: Cystoscopes (to examine the bladder and urethra), Enlarged prostate, Surgery, Catheters, and Kidney stones. Kidney failure also called end stage renal disease or ESRD is also another renal disease when both of kidneys fail. Since the diseases are different one from the other, it is not possible to treat renal system disorders in general.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 and 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 1, the phrase "which may be substituted with a carboxylic acid group" is indefinite. What are covered and what are not? Which acids, or does applicants mean carboxy (-COOH)?

b. In claim 1, the phrase "heterocyclic ring" is indefinite. "Heterocyclic" is indefinite. What is the size of the ring? What is the number and nature of the

heteroatoms? Can the ring be spiroconnected to another ring, and if so, what kind of ring? Can the ring be bridged? Unsaturated? Cf *In re Wiggins*, 179 USPQ 421, 423.

c. In claim 1, one of the choices for R1 is the substituent "alkylene" (7 lines up from the bottom of claim 1), but it is unclear what is meant by the term. What is it? Alkylene is a divalent substituent, but phenyl is monovalent.

d. In claim 1, the phrase "C1 to C4 lower alkyl amino group which may be substituted with carboxylic acid group.." is not clear. It is recommended that applicants amend the claim as follows: "R1 represents (a) hydroxyl, (b) an amino group, (c)...; (a)-(c) may be substituted by carboxylic group..".

e. Claim 6 is rejected because it has no carrier. An active ingredient without a carrier is a duplicate of claim 1. A proper composition claim requires a carrier.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Kahsay Habte, Ph. D.
Examiner
Art Unit 1624

Mark L. Berch
Primary Examiner
Art Unit 1624

KH
April 24, 2002